## REMARKS

#### I. **AMENDMENTS**

Claims 1, 3-41 are currently pending in this application. Claims 1, 3-16, 37-38 are under examination. With this response, claims 1 and 15 have been amended. The non-aspirin, nonsteroidal anti-inflammatory compounds recited in claim 11 has been imported to claims 1 and 15. Claim 11 has been cancelled without prejudice. Applicants respectfully request reexamination and reconsideration of the application in light of the foregoing amendments and following remarks.

### II. **ELECTION RESTRICTION**

The Examiner has made final the election with traverse of Group I claims. tetrahydroisohumulone and ibuprofen. Applicants has previously traversed the election/restriction on the ground that there are only 9 compounds of reduced isoalpha acids and that NSAIDs can easily be searched without excessive burden on the Examiner. The Examiner has found this not persuasive because "all of the claims are not limited to the 9 reduced isoalpha acids that applicant alleges, further NSAIDs encompass many more hundreds of compounds which fall outside of the claimed species found in claims 11 and 12." Office Action, page 2.

In view of the currently amended claims, Applicants respectfully submit that that the Examiner's reasoning for refusing to withdraw the election/restriction is rendered moot. As amended, claims are now limited to a manageable number of species, which should not pose a burden for the Examiner to search them all. Applicants respectfully request that the Examiner withdraw the election restriction and examine the claims for the 9 reduced isoalpha acids and specific NSAIDs listed in claim 1.

#### III. **DOUBLE PATENTING**

Claims are rejected on the ground of non-statutory double patenting over the claims in the following patents or co-pending applications.

- U.S. Patent Application No. 10/789,814 (Applicants' Ref. No. 068911-0075):
- U.S. Patent Application No. 11/344,552 (Applicants' Ref. No. 068911-0138);
- U.S. Patent No. 7,195,785 (Applicants' Ref. No. 068911-0068):

Babish et al.

Application No. 10/557,293 Filing date: Dec. 20, 2006

```
U.S. Patent No. 7,270,835 (Applicants' Ref. No. 068911-0060);
U.S. Patent No. 7,279,185 (Applicants' Ref. No. 068911-0029);
U.S. Patent Application No. 11/344,555 (Applicants' Ref. No. 068911-0141);
U.S. Patent Application No. 11/344,554 (Applicants' Ref. No. 068911-0136);
U.S. Patent Application No. 11/344,556 (Applicants' Ref. No. 068911-0142);
U.S. Patent Application No. 11/344,557 (Applicants' Ref. No. 068911-0139); and
U.S. Patent Application No. 11/344,559 (Applicants' Ref. No. 068911-0137).
```

The Examiner also requires the applicants to list any other patents or applications that they are aware of that may potentially raise obviousness type double patenting issues and file terminal disclaimers to obviate the issues. Applicants are aware of the following patents and applications:

```
U.S. Patent Application No. 11/403,034 (Applicants' Ref. No. 068911-0147); U.S. Patent Application No. 11/344,561 (Applicants' Ref. No. 068911-0140); U.S. Patent Application No. 10/464,410 (Applicants' Ref. No. 068911-0023); U.S. Patent Application No. 10/464,834 (Applicants' Ref. No. 068911-0012); U.S. Patent Application No. 11,729,696 (Applicants' Ref. No. 068911-0180); and U.S. Patent No. 7,431,948 (Applicants' Ref. No. 068911-0148);
```

In order to expedite the prosecution of the application and without acquiescing to the reasoning offered in the Office Action, Applicants herewith submit terminal disclaimers for the above-listed patents and patent applications to overcome the non-statutory double-patenting rejections.

The Examiner is respectfully requested to remove these rejections.

# IV. CLAIM REJECTION UNDER 35 U.S.C. § 112

Claims 1, 3-5, 7-10, 13-15, 37 and 38 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Examiner acknowledges that the compounds of claim 6 and the NSAIDs of claims 11 and 12 have written description. Office Action, page 11, paragraph 2, lines 1-2. However, the Examiner states that "[t]he claims are drawn to a composition comprising a resuced isoalpha acid, dihydro isoalpha acid, tetra hydro isoalpha acid or hexahydro isoalpha acid along with a NSAID (non-aspirin, non-steroidal anti-inflammatory). Thus, the claims are drawn to a genus of compounds which are not completely quantifiable." Office Action, page 9. Applicants respectfully traverse.

According to MPEP § 2163 II,3(a)(ii), the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In the present application, Figure 2 illustrates the chemical structures of reduced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids. Figures 3C-3E further provide chemical structures of representative species of these compounds in which the "R" group may vary as described in the description of Figure 3, on page 7. The physical characteristics (e.g., derived from hops) and chemical properties (e.g., being in reduced form) of the genus and the representative species of the genus are further described on page 7, paragraph 2 to page 19, paragraph 2. The functional characteristic of these compounds as cyclooxygenase-2 (COX-2) inhibitors are also described throughout the application and at, for example, Example 3. The Examples further disclose correlation between function and structure for these compounds.

Having disclosed structure, function, and working examples that correlate the structure and function, the specification provides sufficient written description for a skilled artisan to predict the operability in the invention of any and all species of the of compounds selected from the group consisting of resuced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids, other than the ones disclosed. As such, Applicants respectfully submit that they were in possession of the invention as claimed with respect to the genus of compounds selected from the group consisting of resuced isoalpha acids, dihydro isoalpha acids, tetra hydro isoalpha acids and hexahydro isoalpha acids.

As for the genus of non-aspirin, non-steroidal anti-inflammatory compounds (NSAIDs), without acquiescing to the reasoning offered in the Office Action, Applicants have amended claim 1 to include the specific NSAID species previously recited in claim 11.

Babish et al.

Application No. 10/557,293

Filing date: Dec. 20, 2006

As such, and based on the foregoing remarks, Applicants respectfully submit that they

were in possession of the invention as claimed and request the withdrawal of this rejection.

V. **CONCLUSION** 

In light of the amendments and remarks herein, Applicants submit that the claims are

now in condition for allowance and respectfully request a notice to this effect. If there are any

outstanding issues that might be resolved by an interview or an Examiner's amendment, the

Examiner is requested to call Applicant's agent at the telephone number shown below.

The Commissioner for Patents is authorized to charge any fees required under 37 C.F.R.

1.20(d), for the terminal disclaimers filed herewith, to deposit account 50-1133.

A Request for a Three (3) Month Extension of Time, up to and including August 10,

2009, is included herewith. Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to

charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future

communications, to Deposit Account 50-1133. Furthermore, such authorization should be

treated in any concurrent or future reply requiring a petition for an extension of time under

paragraph 1.136 for its timely submission, as constructively incorporating a petition for

extension of time for the appropriate length of time pursuant 37 C.F.R. § 1.136(a)(3) regardless

of whether a separate petition is included.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Dated: August 7, 2009

Atabak R. Royaee, Reg. No. 59,037

McDERMOTT WILL & EMERY LLP

28 State Street

Boston, MA 02109-1775

Tel. (617) 535-4108

Fax: (617) 535-3800

-14-